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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,456	07/03/2001	Carl Johan Friddle	LEX-0198-USA	8160

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/898,456	Applicant(s) FRIDDLE ET AL.	
	Examiner Robert C. Hayes, Ph.D.	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5 and 9-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5 and 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of Group III (claims 1, 5 & 6) in Paper No. 11/10/03 is acknowledged. Deletion of inventor Erin Aylor due to the restriction requirement is acknowledged.

Claim Rejections - 35 U.S.C. § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 11 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. For example, the current recitation of "A host cell" encompasses a human organism. It is noted that "gene therapy" is contemplated, for example, on page 15 of the specification. Therefore, it is suggested that amending the claims to "an isolated host cell" should obviate the rejection of claim 11.

3. Claims 1, 5 & 9-11 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility.

Pages 1-2 of the specification disclose that "[t]he novel human proteins (NHPs) described for the first time herein share structural similarity with animal WNT proteins and particularly WNT-8D". WNT proteins are described as being "soluble secreted proteins that have been implicated in intercellular signaling during vertebrate (especially spinal cord) development", and "[a]s such, WNT proteins have been implicated in a number of neural processes and anomalies".

Art Unit: 1647

In contrast, not a single specific and assayable function is disclosed for the polynucleotide of SEQ ID NO: 6 encoding the polypeptide of SEQ ID NO: 7. Pages 16 & 18 of the specification then disclose that “NHPs... can be prepared for a variety of uses” and used “for treating biological disorders”. In contrast, not a single specific disease state that putatively can be treated by using these “novel human proteins (NHPs) described for the first time herein” is disclosed; especially as it relates to the encoded polypeptide of SEQ ID NO: 7. Moreover, because many genes are putatively important in “treating biological disorders” or “implicated in intercellular signaling during vertebrate (especially spinal cord) development”, or “implicated in a number of neural processes and anomalies”, no “specific” utility exists, because the specific biological activity for even the encoded polypeptide depicted as SEQ ID NO: 7 is not known nor specifically described within the specification, and therefore, one cannot reasonably extrapolate what constitutes a specific utility for the polynucleotide of SEQ ID NO: 6.

Secondly, because no specific utility is described or known for the human NHP polynucleotide of SEQ ID NO: 6, and because Applicants merely generically prophesize that the polynucleotide of the instant invention may be useful “for treating biological disorders”, which are further unknown and not disclosed at the time of filing Applicants’ invention, the instant invention also has no “substantial utility” because further experimentation is necessary at the time of filing the instant invention to attribute and discover a “real world” utility to the polynucleotide of SEQ ID NO: 6.

Applicant is directed toward the Utility Guidelines in MPEP 2107. See especially MPEP 2107.03.

Art Unit: 1647

Claim Rejections - 35 U.S.C. § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5 & 9-11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.

February 3, 2004

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